

**REMARKS**

**Status of the Claims**

Claims 1-8 and 11-19 are pending in this application. No claims have been canceled. Claims 18 and 19 have been added. Claims 1 and 11 have been amended to define the specific types of oils in the composition. Support for the claim amendments is found in the specification at page 3, lines 14-15. Applicants submit that no new matter has been added by the above claim amendments.

**Rejection under 35 USC 102(b)**

The Examiner rejects claims 1-3 and 6 as anticipated by JP 62-592019 (JP '019). Applicants traverse the rejection and respectfully request the withdrawal thereof.

The present invention is directed to a migraine-alleviating drug composition consisting of l-menthol and one or more essential oils, such as lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil as active ingredients in a pharmaceutically base. The composition may be in an ointment or patch form. The present invention is also directed to a method of treating migraine with the claimed drug composition.

JP '019 discloses an external drug composition such as, antitussives, expectorants, analgesics and sedatives. The composition of JP '019 contains dl-camphor, l-menthol, nutmeg oil and fennel oil. The composition of JP '019 may also contain turpentine oil and/or eucalyptus oil. JP '019 exemplifies l-

menthol and nutmeg oil as essential ingredients in an analgesic composition. The antitussive effect of the composition of JP '019 is attained by the nutmeg oil and fennel oil working synergistically with the dl-camphor and l-menthol. See page 3, lines 12-16.

JP '019 fails to disclose or suggest using lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil as an essential ingredient as in the present invention. There is no motivation or suggestion to use one of the oils of the present invention as a substitute for nutmeg oil.

JP '019 also fails to disclose treatment of migranes. At best, JP '019 teaches an analgesic composition that relieves headache, cough, nasal congestion and throat pain due to the common cold.

Applicants also point out that the experimental results in JP '019 are skeptical regarding the effectiveness of the analgesic on guinea pigs. See page 4, line 2 where it is disclosed that l-menthol is excellent in analgesic. However, in Table 3 of the present specification in the comparative testing l-menthol alone was tested for migraine alleviation and l-menthol alone was not effective. Please also see Goodman & Gilmann and the Handbook of Nonprescription Drugs copies are enclosed for your convenience. These references clearly point out the differences between a mere headache that is associated with the common cold and a migraine.

Applicants also point out that the addition of the essential oils of the present composition are not to merely mask an unpleasant odor as suggested by the Examiner. In fact, the odor of l-menthol is an important factor in the effectiveness of the present invention and should not be masked.

As such, Applicants submit that the present invention is not anticipated by JP '019 because JP '019 fails to disclose all the essential limitations of the present invention. Thus, Applicants respectfully request that the rejection be withdrawn.

**Rejection under 35 USC 103(a)**

The Examiner rejects claims 4, 5, 7, 8 and 11-17 as obvious over JP '019. Applicants traverse the rejection and respectfully request the withdrawal thereof.

Applicants rely on the above arguments regarding anticipation to traverse the obviousness rejection. Applicants submit that JP'019 also fails to suggest the specifically claimed oils in combination with the other essential components of the claimed composition. As such, Applicants submit that the present invention is also not obvious over JP '019 and the rejection should be withdrawn.

**Conclusion**

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Attached hereto is a marked-up version of the changes made to the application by this Amendment.


If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

(Rev. 02/20/02)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

1. (Three times Amended) A migraine-alleviating drug composition suitable for external application, consisting essentially of:

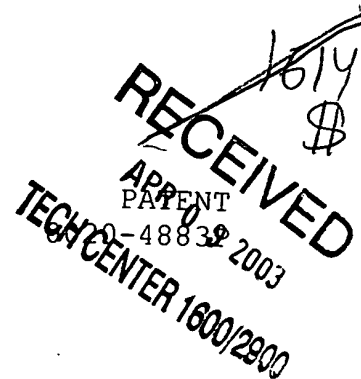
active ingredients consisting of l-menthol and one or more essential oils selected from the group consisting of lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil; and a pharmaceutically acceptable base.

11. (Three times amended) A method for alleviating migraine comprising the step of:

administering to a patient in need thereof an effective amount of a drug composition consisting essentially of as active ingredients l-menthol and one or more essential oils selected from the group consisting of lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil in a pharmaceutically acceptable base; and

wherein said drug composition is dermally administered.

Claims 18-19 have been added.



Applicant: Hideakira YOKOYAMA et al. Conf.: 4627  
Appl. No.: 09/890,552 Group: 1614  
Filed: August 2, 2001 Examiner: D.A. JAGOE  
For: DRUG FOR ALLEVIATING MIGRAINE

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

- ☐ The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.
- ☐ The enclosed document is being transmitted via facsimile.

The fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL	17	-	20	=	0	\$18	\$0.00
INDEPENDENT	4	-	3	=	1	\$84	\$84.00
<input type="checkbox"/> FIRST PRESENTATION OF A MULTIPLE DEPENDENT CLAIM						\$280	\$0.00
						TOTAL	\$84.00

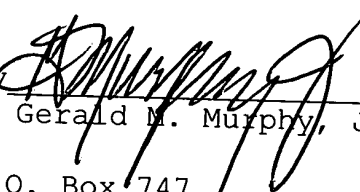
Appl. No. 09/890,552

- ☒ Petition for one (1) month(s) extension of time pursuant to 37 C.F.R. §§ 1.17 and 1.136(a). \$110.00 for the extension of time.
- ☐ No fee is required.
- ☒ A check in the amount of \$194.00 is(are) enclosed.
- ☐ Please charge Deposit Account No. 02-2448 in the amount of \$0.00. This form is submitted in triplicate.


If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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0020-4883P

Attachment(s)

(Rev. 10/15/02)